10/553812 -11/553.812

Application No.:
Amendment Date:

26 Jun 2008

Reply to Office Action of:

28 Mar 2008

REMARKS/ARGUMENTS

Claims 1-14 are pending.

Claims 1, 8, 9, 10, 11, and 12 have been amended as suggested by the Examiner to consistently recite the designation of the rhesus monkey bombesin receptor subtype-3 as "rhBRS-3".

Claim 1 was further amended to recite that the isolated nucleic acid molecule, comprises the sequence of nucleotides that encodes the rhesus monkey BRS-3 (rhBRS-3) protein as set forth in SEQ ID NO:2.

Claim 5 was amended to recite that the isolated nucleic acid molecule of claim 1 comprises the sequence of nucleotides as set forth in SEQ ID NO:1.

Claim 6 was amended to correct the spelling of "expression".

Claims 7, 12, and 14 were amended as suggested by the Examiner to recite that the "host cells" or "cells" are "isolated host cells" or "isolated cells".

Claim 10 was further amended to recite that the isolated and purified rhesus monkey bombesin receptor subtype-3 (rhBRS-3) polypeptide comprises the sequence of amino acids as set forth in SEQ ID NO:2.

Claim 11 was amended to recite that a method for identifying compounds that modulate rhesus monkey bombesin receptor subtype 3 (BRS-3) expression rhBRS-3 activity, comprising contacting a test compound with the rhBRS-3 protein polypeptide of claim 10, and determining whether the test compound interacts with rhesus monkey bombesin receptor subtype 3 modulates activity of the BRS-3 polypeptide. Support for this amendment can be found throughout the specification, for example, in the paragraph bridging pages 15-16, in the paragraph beginning at line 4 on page 16, and in the paragraph beginning at line 15 on page 14.

The specification has been amended as suggested by the Examiner to change the descriptions for Figures 3 and 4 to Figures 3A, 3B, 3C, 3D, 4A, and 4B, respectively.

The amendments to the claims and specification are not believed to have introduced new matter into the application.

I. Objection to the Specification

The specification has been amended as suggested by the Examiner to correct the descriptions of Figures 3 and 4. In light of the amendments, reconsideration of the objection is requested.

II. Objection to Oath/Declaration

Application No.: Amendment Date:

26 Jun 2008

Reply to Office Action of:

28 Mar 2008

A new Declaration is in the process of being executed and will be forwarded to the Examiner when available.

III. Objections to the Claims

Claims 1 and 8-14 were objected to for the inconsistent designation of the rhesus monkey bombesin receptor subtype-3 abbreviations.

The claims have been amended in the manner suggested by the Examiner. In light of the amendments, reconsideration of the objection is requested.

Claim 13 was objected to for the term "combining" with respect to "combining a test substance in the presence or absence of the rhBRS-3" because in the absence of the rhBRS-3, it is not clear what the test substance will be combined with.

The claim has been amended to recite "A method of identifying a substance which modulates rhBRS-3 receptor activity, comprising: (a) combining contacting a test substance in the presence and absence of the rhesus monkey rhBRS-3 protein of claim 10 with a test substance; and, (b) measuring and comparing the effect of the test substance in the presence and absence of on the activity of the rhBRS-3 receptor protein." It is believed that the amendments to Claim 13 have addressed the issue raised by the Examiner. Reconsideration of the rejection is requested.

IV. Rejection of Claims 7, 12, and 14 under 35 USC § 112, first paragraph, enablement Claims 7, 12, and 14 were rejected under 35 USC, first paragraph, for allegedly lack of enablement. The rejection states that "the specification, while being enabling for (1) an isolated host cell comprising the vector of claim 6; and (2) a method of screening using said isolated host cell, does not reasonably provide enablement for (3) a host cell comprising the vecot of claim 6 or (4) a method of screening using said host cell. The specifications does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims." The Examiner has indicated that the rejection could be overcome by amending the claims to recited "an isolated host cell' . . . because such an amendment would clarify that the claims are directed only to host cells that are to be made and used in culture."

Claims 7, 12, and 14 have been amended without prejudice to indicate that the cells are "isolated" host or test cells (Claims 7 and 12, respectively) or "isolated" cells are transfected (Claim 14). Currently amended Claims 7, 12, and 14 are believed to satisfy

Application No.:
Amendment Date:

26 Jun 2008

Reply to Office Action of: 28

28 Mar 2008

enablement requirement of 35 USC § 112, first paragraph. Reconsideration of the rejection is requested.

V. Rejection of Claim 11 under 35 USC § 112, first paragraph, enablement

Claim 11 was rejected under 35 USC § 112, first paragraph, for allegedly lack of enablement. The rejection states that Claim 11 is drawn to a method for identifying compounds that modulate rhBRS-3 expression comprising contacting a test compound with the rhBRS-3 protein of Claim 10. The rejection states that the method does not enable the skilled artisan to achieve the preamble recited in the claim because identifying compounds that interact with the rhBRS-3 protein does lead to identification of compounds that modulate expression of the rhBRS-3.

Claim 11 has been amended to recite "A method for identifying compounds that modulate rhesus monkey bombesin receptor subtype 3 (BRS-3) expression rhBRS-3 activity, comprising contacting a test compound with the rhBRS-3 protein polypeptide of claim 10, and determining whether the test compound interacts with rhesus monkey bombesin receptor subtype 3 modulates activity of the BRS-3 polypeptide." It is believed that the amendments have removed the basis for the rejection. Reconsideration of the rejection is requested.

VI. Rejection of Claims 1-3 under 35 USC § 102(b)

Claims 1-13 were rejected under 35 USC § 102(b) as being anticipated by <u>Lane</u> et al., U.S. Patent No. 6,143, 521.

The rejection states that "the phrase used in Claim 1 ('a sequence of nucleotides that encodes a rhesus monkey BRS-3 protein as set forth in SEQ ID NO:2') encompasses nucleic acid molecules that encode any shorter amino acid sequence found with SEQ ID NO:2..."

The rejection states that the "'521 patent teaches a protein sequence... that is 96.5% identical to instant SEQ ID NO:2 and contains numerous shorter sequences that are 100% identical to subsequences in instant SEQ ID NO:2...." The same rational was applied to claims relying upon SEQ ID NO:1. Thus, the rejection alleges that Claims 1-13 are anticipated by Lane.

The applicants have amended Claims 1, 5, and 10 and believe that the currently amended claims are not anticipated by <u>Lane</u>. Claim1 has been amended to recite "An isolated nucleic acid molecule, comprising <u>the</u> sequence of nucleotides that encodes a rhesus monkey BRS-3 (rhBRS-3) protein as set forth in SEQ ID NO:2." [emphasis added]. Claim 5 has been amended to recite "The isolated nucleic acid molecule of claim 1 wherein the sequence of nucleotides comprises <u>the</u> sequence of nucleotides as set forth in SEQ ID NO:1." [Emphasis

Application No.:
Amendment Date:

11/553,812 26 Jun 2008

Reply to Office Action of:

28 Mar 2008

added]. Claim 10 has been amended to recite "An isolated and purified rhesus monkey bombesin receptor subtype-3 (rhBRS-3) polypeptide comprising the sequence of amino acids as set forth in SEQ ID NO:2. [emphasis added].

In light of these amendments, the applicants claimed nucleic acid molecule in currently amended Claim 1 does not encode a protein that has an amino acid sequence that is identical to the amino acid sequence disclosed in <u>Lane</u> and the nucleic acid molecule in currently amended Claim 5 does not have a nucleotide sequence that is identical to the nucleotide sequence disclosed in <u>Lane</u>. The amino acid sequence of the polypeptide in currently amended Claim 10 is not identical to the amino acid sequence disclosed in <u>Lane</u>. Therefore, the sequences disclosed in <u>Lane</u> do not anticipate the nucleotide sequence or the amino acid sequence of currently amended Claims 1-13. Reconsideration of the rejection is requested.

VII. Rejection of Claim 14 under 35 USC § 103(a)

Claims 14 was rejected under 35 USC § 103(a) as being obvious over <u>Lane</u> et al., U.S. Patent No. 6,143, 521.

The rejection states that "the '521 patent teaches host cells comprising an expression vector encoding a nucleic acid of Claim 1, and expression of the protein using said host cells. The '521 patent further teaches screening using 'competition with a labeled competitor'. The '521 patent further teaches antibodies to the polypeptide of the invention. As antibodies bind to the polypeptide, they are encompassed by the term 'ligand' used in Claim 14. Lane does not specifically teach using a 'labeled ligand' as the 'labeled competitor'." The rejection concludes "It would have been obvious to the person of ordinary skill in the art at the time the invention was made to use an antibody (which is a species of labeled ligand) taught by Lane as a labeled competitor in a method of competitive screening with a test compound as taught by Lane. The person of ordinary skill in the art would have been motivated to make that modification in order to have a labeled competitor for use in the screening taught by Lane."

The applicant respectfully disagrees with the rejection. Currently amended Claim 14 recites a method for determining whether a substance is a potential agonist or antagonist of rhBRS-3 wherein <u>isolated</u> cells are transfected or transformed with the expression vector of claim 6. Claim 6 incorporates the nucleic acid molecule of Claim 1, which comprises "the sequence of nucleotides that encodes a <u>the</u> rhesus monkey BRS-3 (<u>rhBRS-3</u>) protein as set forth in SEQ ID NO:2." As discussed above, <u>Lane</u> does not anticipate currently amended Claim1 and thus currently amended Claim 6. Because Claim 14 uses a vector encoding a protein unknown to <u>Lane</u> and which has an amino acid sequence that would not have been predicted based upon the

Application No.:
Amendment Date:

26 Jun 2008

Reply to Office Action of:

28 Mar 2008

disclosure of <u>Lane</u>, it is believed that currently amended Claim 14 is not obvious over <u>Lane</u>. Thus, a person of ordinary skill in the art in view of <u>Lane</u> would not have been able to derive a method for determining whether a substance is a potential agonist or antagonist of rhBRS-3 wherein <u>i</u>solated cells are transfected or transformed with the expression vector of claim 6, which expresses a protein having the amino acid sequence set forth in SEQ ID NO:2.

In light of the above, currently amended Claim 14 is believed to be non-obvious and patentable over <u>Lane</u>. Reconsideration of the rejection is requested.

In view of the foregoing amendments and remarks, it is believed that the grounds of rejections have been overcome and that the claims are in proper condition for allowance. Accordingly, Applicants respectfully request that all of the rejections be withdrawn and a Notice of Allowance be forwarded to the Applicants. The Examiner is invited to contact Applicants' Attorney at the telephone number given below, if such would expedite the allowance of this application.

Favorable action is earnestly solicited.

CONDITIONAL PETITION

Applicant hereby makes a Conditional Petition for any relief available to correct any defect in connection with this filing, or any defect remaining in this application after this filing. The Commissioner is authorized to charge deposit account 13-2755 for the petition fee and any other fee(s) required to effect this Conditional Petition.

Respectfully submitted,

John David Reilly Reg. No. 43,039

Attorney for Applicant

MERCK & CO., INC.

P.O. Box 2000

Rahway, New Jersey 07065-0907

(732) 594-6914

Date:

24,2008

Page 10 of 10